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| 09/886,327 | 06/21/2001 | James Allen McEwen | 1077-023-PWH | 6889 |

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BUI, VY Q

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| ART UNIT | PAPER NUMBER |
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3734

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,327

Applicant(s)

MCEWEN, JAMES ALLEN

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-13,15-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-13,15-17 and 19, 21-22 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5-6, 11, 15 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over SMITH and NEPHEW RICHARDS' cuff (now is SAMMONS PRESTON ROLYAN, Bolingbrook, Illinois).

Regarding claims 1, 5-6, 11, 13, 15 and 18, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee discloses a pair of a tourniquet cuff and a stockinette sleeve and inherently a method of using the pair of the tourniquet cuff and the stockinette sleeve. The pair comprises a color coded tourniquet cuff having a length sufficient for encircling a limb having a limb circumference within a range of not less than a predetermined minimum (cuff overlap about four inches, first page, SMITH and NEPHEW RICHARDS) and not more than a predetermined maximum (cuff overlap about three inches, first page SMITH and NEPHEW RICHARDS), and the color code is indicative of the circumferential range (see list of color coding on third page,

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SMITH and NEPHEW RICHARDS' disposable cuffs), a stretchable protection sleeve/stockinette sleeve made of stockinette applied to the limb such that the sleeve circumference should be less than the limb's circumference to avoid any wrinkles in the stockinette sleeve (item 4, page 1, SMITH and NEPHEW RICHARDS), and instrument for pressurize the cuff.

As admitted by the Applicant in the "Argument" section (page 6 of 14, first paragraph) "Smith & Nephew Richards apparently packs together a cuff and a sleeve", so there exists a step of matching the cuff and the stockinette sleeve. Alternatively, one of ordinary skill in the art can provide a mark/an alpha numeric code/color code on an associate stockinette sleeve to help a physician to select and match a stockinette sleeve to use with a specific cuff.

Notice that the practice of using alphabet/numeric/color coding is well known for matching two components together. For example, two matching shoes of a pair have the same color (black or brown, for example) and same number to indicate the same size.

Further, Smith et al.-4,650,475 (Fig. 1; col. 1, lines 50-52; col. 2, lines 4048) discloses a pair of encoded cuff 24 and sleeve 30 for matching the two together. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide a code for matching a pair of cuff and sleeve of SMITH and NEPHEW RICHARDS so that one can match the two quickly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 8-10, 12-13, 16-17, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over SMITH and NEPHEW RICHARDS, Inc. (now is SAMMONS PRESTON ROLYAN, Bolingbrook, Illinois).

As to claim 2-3, 7, 12-13 and 22, SMITH and NEPHEW RICHARDS does not expressly disclose same color-coding for a pair of a cuff and an associate sleeve. However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to mark both a cuff and an associate sleeve with the same color to help a user to identify and match quickly a separate cuff and its associate sleeve and avoid a use of a pair a cuff and a unmatched sleeve, which could render a tourniquet procedure less effective.

As to claims 4 and 17, SMITH and NEPHEW RICHARDS does not disclose a separate sealed package for a matching pair of a cuff and a sleeve. However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to put a pair of a cuff and an associate sleeve in a package, such as a sealed plastic bag, so as to pre-select the right pair of a cuff and an associate sleeve for a user.

As to claims 8-10, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee discloses substantially all limitations as recited in the claims except the manner in which the sleeve is constructed to carry the color code thereon. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct the sleeve as claimed for this is just one way to make the sleeve and this construction would make no critical effect to the performance of the device.

As to claim 21, it would have been obvious to one of ordinary skill in the art to measure the pressure applied to a limb by the sleeve so that one can determine the pressure of the sleeve on the limb.

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As to claim 22, because the size/dimension of the sleeve does not seem critical to the performance of the device, the size/dimension of the sleeve as recited in the claim appears as just a design choice.

3. Claims 16, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee.

Regarding claims 16, 19, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee does not disclose the stockinette sleeve applying a pressure less than a predetermined pressure of about 2 mmHg on the limb. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make experiments to determine the optimum value predetermined pressure of 2 mmHg since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Allowable Subject Matter

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

In response to Applicant's arguments, it is clearly that:

1. the cuff of SMITH and NEPHEW RICHARDS is color encoded

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2. a cuff and a sleeve are packed and used as a pair, therefore, a matching step exists for matching a cuff and a sleeve so that they can be used together as a pair.

3. even if a sleeve of SMITH and NEPHEW RICHARDS is not color coded, it would have been obvious to one of ordinary skill in the art to do so, so that one can quickly match a sleeve to an associated color coded cuff.

4. the specific features as recited in claims 13, 22 (width of the sleeve), 8-10 (sleeve of dual layer, folded design),

Therefore, the claimed invention is not patentable over SMITH and NEPHEW RICHARDS.

Conclusion

SMITH et al (4,650,475) discloses same color coding of a cuff and a sleeve in a medical device was provided in the previous non-final "Office Action".

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

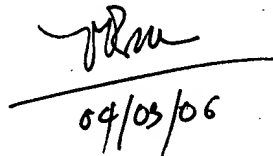
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Handwritten signature of Vy Q. Bui, dated 04/03/06.

Vy Q. Bui
Primary Examiner
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